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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/695,559 | 10/28/2003 | Karl Tryggvason | 02-1147-US | 3784 |

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| EXAMINER | |
|---|---|
| HINES, JANA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/695,559 | TRYGGVASON ET AL. | |
| | Examiner | Art Unit | |
| | Ja-Na Hines | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 10/28/05.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 are drawn to a method for inhibiting tumor growth, classified in class 424, subclass 277.1.

II. Claims 5-8 are drawn to an isolated antibody, classified in class 436, subclass 548.

III. Claims 9-10 are drawn to a pharmaceutical composition comprising an antibody and an anti-tumor agent, classified in class 424, subclass 138.1.

IV. Claims 11-14 are drawn to a method of inhibiting tumor growth and/or metastasis, classified in class 424, subclass 573.

V. Claim 15 is drawn to a method for detecting the presence of invasive cells in a tissue, classified in class 435, subclass 7.23.

2. The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and either IV or V are related as distinct methods because they are different methods with different method steps; reagents; functions and each result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification states that the methods are separate and distinct and represented within different embodiments. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. For instance, one method detects the presence of invasive cells, while another method only inhibits tumor

growth. Second, each invention performs its function using a structurally and functionally divergent material. For instance, the method of detection uses an antibody which is different from the antibody used in group I. In this case, group I is separate and distinct, from groups IV and V, since only group I comprises using an antibody that does not bind to the epitopes within the amino acid sequences of SEQ ID NO:9 and 10. Therefore, each method is divergent with respect to the reagents used and their associated steps. For these reasons the inventions I, IV and V are patentably distinct.

Furthermore, searching the inventions of groups I, IV and V would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A method for detecting the presence of invasive cells requires a different search, than for a search drawn to a method for inhibiting tumor growth and metastasis. Thus, a search drawn to a method for screening for antimicrobial compounds is not necessary for a determination of novelty and unobviousness of the method of group IV which comprises a method for inhibiting tumor growth and metastasis. Furthermore, the method of group I may be known even if the method of group IV is novel. In addition, the technical literature search for the method of group I and the method of groups IV and V are not coextensive, since, for instance, the method group I may be characterized in the technical literature prior to discovery of the method of group IV

b) Inventions II and III are patentably different products. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive

groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions. Group II is drawn to an isolated antibody while group III is drawn to a pharmaceutical composition comprising an antibody and an anti-tumor agent. The groups are directed products which are distinct physically, structurally and functionally, and are therefore patentably distinct, each group from the other. For instance, the antibody of Group II is unlike the composition of Group III, even though both contain an antibody. Moreover, only the antibody of group II does not bind to epitopes within the amino acid sequences of SEQ ID NO:9 and 10. Thereby, making the antibody of Group II distinct from the composition of Group III. Therefore, one product is not required to practice the other. Each group comprises separate and distinct products that are not disclosed as being essential to the utility of the invention.

Furthermore, searching the inventions of groups II and III would impose a serious search burden. The inventions have a separate status in the art as shown by their distinct structure. Thus different products require different searches. An amino acid sequence search of SEQ ID NO:9 and 10 is not necessary for a determination of novelty and unobviousness of the unrelated pharmaceutical composition of group III. Moreover, a search of group II is not required to identify the composition of group III. Furthermore, the antibody of group II may be known even if the composition of group III is novel. In addition, the technical literature search for the antibody of group II is not coextensive, e.g., the antibody of group II may be characterized in the technical literature prior to discovery of the composition of group III.

c) Inventions I and either III or V are unrelated because the product of group III us not used or otherwise involved in the processes of groups I or V.

d) Inventions II and IV or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of group II can be practiced with a materially different process such as with a method of inducing an immune response in a subject. Therefore, the inventions have been shown as distinct.

Searching the inventions of groups I and either IV or V together would impose serious search burden. The inventions of groups I and either IV or V have acquired a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibody and the method for detection are not coextensive. Group IV is drawn to a method of inhibiting tumor growth and metastasis, and therefore not required for the search of groups I or V. In contrast, the search for groups V would require a text search for a method for detecting the presence of invasive cells in a tissue and would not necessarily encompass a search for the method of inhibiting tumor growth and metastasis. Moreover, even if the antibody product were known, the method for detection or inhibiting tumor growth and metastasis may be novel and unobvious in view of the preamble or active steps.

3. The inventions of Groups I-V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-V together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 20, 2005